

#### **IV. REMARKS/ARGUMENTS**

##### **A. Status of the Claims**

Claims 11-35 are pending. Claims 1-10 have been cancelled, without prejudice. Claims 12, 13, 20-26, 32 and 34 are withdrawn from consideration. Claims 11, 14-19, 27-31, 33 and 35 stand rejected. Applicants has amended claims 11, 15 and 35. No new matter is introduced by these amendments, and these amendments are fully supported by the specification. Applicants respectfully request reconsideration of the rejections of these claims for at least the following reasons.

##### **B. Objection To The Drawings**

The drawings stand objected to for including reference characters that are not mentioned in the specification. Specifically, elements 220 and 230 in Figure 2 are not described in the written description. In response, Applicants have amended paragraph 0055 to include these elements. No new matter is introduced by this amendment.

The drawings also stand objected to for allegedly failing to show every feature specified in the claims. Specifically, the Office Action alleges that the drawings do not show the "continuous blade" and the "blade take-up canister." Applicants respectfully disagree.

With regard to the continuous blade, with reference to Fig. 3, the application states:

The blades of first blade assembly 346 and second blade assembly 342 are each stored within the respective blade supply canisters, 306 and 310. The blade may be continuous roll of blade material. Further, both blade assemblies 346 and 342 may be driven by blade

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supply motor 308. A blade take-up canister may be provided for each blade supply canister 306 and 310 to received the used blade.

Appl'n, ¶ 0088 (emphasis added). Therefore, as the claimed "continuous blade" is illustrated in the figures, Applicants respectfully request that this objection be withdrawn.

Although Applicants do not necessarily agree with the objection regarding the claimed "blade take-up canister," in an effort to expedite the prosecution of the present application, Applicants have amended claims 15 and 35. This objection is not moot.

### **B. Objections To The Claims**

Claims 11 and 15 stand objected to for informalities. Specifically, the Office Action asserts

On line 8 of claim 11, the phrase "said slicing means" should be replaced with "said blade assembly" for consistency. On lines 8 and 11 of claim 11, the phrase "a thin section" should be replaced with "said thin section". On line 11 of claim 11, the phrase "said plurality" should be replaced with "said plurality of transfer rollers". On line 1 of claim 15, the phrase "said slicing means" should be replaced with "said blade assembly"

Office Action, Page 4. In response, Applicants have amended claims 11 and 15 accordingly.

### **C. Claim Objections Under 35 U.S.C. § 112, ¶ 1**

Claims 16-18 and 35 stand rejected under 35 U.S.C. § 112, ¶ 1 for allegedly failing to comply with the enablement requirement. With regard to claims 16 and 35, the Office Action asserts:

In regards to claims 16 and 35, page 10 lines 16 of the specification states the "blade may be continuous". In order for the blade to be

continuous it would have to incorporate a loop-type structure similar to a band saw blade. However, using Figure 3, it is unclear how the apparatus could function with a loop-type blade. The cutting or top portion of the loop would go over top the wall structure separating the first and second canisters but it is unclear how the return or bottom portion of the loop would be able to return. Basically it is unclear how a continuous blade could be used when the apparatus appears only to be able to function with a non-continuous blade. It is requested that applicant's response to this Office action include a description of how the blade assembly and blade canisters work. Since one skilled in the art may understand how the cutting system works, a rejection is not proper. The description needs only to be in the "remarks" section of the next response to help the examiner better understand/examine the instant application.

Office Action, Pages 4-5. Applicants respectfully disagree.

Applicants have not used the word "continuous" to describe a loop-type blade, such as a band saw blade. Rather, the specification describes the continuous blade as follows:

In one embodiment, a continuous blade is supplied in a blade supply canister, incrementally advanced during the operation, and stored on a blade take-up canister. The continuous blade may be continuous roll of any suitable blade material. The blade assembly may be driven by a blade supply motor.

The blade may be advanced at predetermined intervals, such as the number of slices the particular section of blade has made. In another embodiment, the blade may advance when the sample block is changed. Other suitable criteria may also be use in order to ensure that the blade produces histologic grade slices. The blade may be incrementally advanced automatically, or it may be done manually by the technician.

Blade stock is accordingly incrementally rewound on spindles in the blade take-up canister. When the blade stock runs out, the empty blade supply canister is replaced with a fresh blade supply canister, and the used blade is discarded.

Appl'n, ¶¶ 0048-50.<sup>1</sup> The specification discloses the "non-continuous," or "fixed" blade as follows:

In another embodiment, standard fixed blades of a suitable material may be used. These materials may include the same materials used for the continuous blade. These fixed blades may be replaced automatically, or they may be replaced manually by the technician

Appl'n, ¶ 0092. Thus, the difference between a "continuous" and a "non-continuous" blade is that the "continuous" blade is advanced in increments, and may be provided in a blade supply canister, and stored in a blade take-up canister. Therefore, Applicants respectfully request that this rejection be withdrawn.

With regard to claim 17, the Office Action asserts:

the limitation "an optical sensor for automatically determining an orientation of said tissue sample" is unclear. Assuming the "optical sensor" is the same structure as optical imaging system 348, the specification (page 17 lines 28-29) discloses "the location of the tissue sample within the paraffin block is determined by optical imaging system". There is no support in the specification that the optical sensor determines anything other than the location of the tissue sample.

Office Action, Page 5. Applicants respectfully disagree.

Applicants submit that there is sufficient disclosure in the specification that the optical sensor determines the location and orientation of the sample within the sample block. Specifically, the specification discloses:

In step 106, the position of the tissue sample within the prepared sample block that is in the holding assembly is determined. In the manual process, the general angle of the tissue sample in the sample

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<sup>1</sup> Note that the paragraph references are to U.S. Patent App. Pub. No. 2003-0022271 A1.

block is determined by the technician when the paraffin wax hardens. In order to achieve the best slice of the sample tissue, it is generally desirable to present the maximum surface area of the tissue sample to the blades. If a sample block contains multiple tissue samples, it is generally desirable to orient the sample block so that the tissue samples are all at the same approximate depth with respect to the blade.

Any device or method that determines the depth and general mount angle of the tissue sample may be used. In one embodiment, an optical imaging system is used. This may include optical scanning devices using, e.g., focused light beams or lasers. Other methods and devices for determining the location of the tissue sample, such as RF waves, sonar, radar waves, X-rays, magnetic resonance, interferometers, etc., may also be used. In one embodiment, the optical imaging system locates the position and orientation of the tissue sample in the sample block in sufficient detail to permit the system controller to determine the desired orientation of the sample relative to the blade. Once the sample is optically scanned, the resulting data may be sent to the system controller, which processes the data in order to determine the appropriate orientation of the sample block.

Appl'n, ¶¶ 0042-43 (emphasis added). Therefore, in view of this disclosure, Applicants respectfully request that this rejection be withdrawn.

**D. Claim Rejections Under 35 U.S.C. § 102(b)**

Claims 11, 14, 27, 29, 31 and 33 stand rejected under 35 U.S.C. § 102(b) as allegedly anticipated by U.S. Patent No. 5,156,019 to McCormick. Specifically, with regard to independent claim 11, the Office Action asserts:

McCormick discloses the same invention including a blade assembly for slicing thin section from a work piece (18), a plurality of transfer rollers sequentially arranged in tangential proximity to each other (40a, 48, and 40), a thin section on the surface of one transfer roller will be transferred to the surface of the sequentially successive transfer roller (40 Fig. 1, it is noted that item A need not be directly in contact with item B to be considered on the surface of item B. For example, if three books were stacked, the highest book is still on the

surface of the lowest book via the middle book), a first sequential transfer roller is oriented in proximity to the slicing means (40a) so that a thin section sliced from the work piece will contact the surface of the first sequential transfer roller (26 contacts belt 24 which contacts roller 40a, therefore 26 contacts the surface of 40a), and a receiving medium (62) disposed in tangential proximity to a final sequential transfer roller (far right 40) so that the thin section on the surface of the final sequential roller will be transferred to the receiving medium in a substantially smooth and flat configuration (occurrence of 26 to the right of 40).

Office Action, Page 6. Applicants respectfully disagree.

In order for a claim to be anticipated by a reference, that reference must disclose each and every element of the claimed invention. *See Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631 (Fed. Cir. 1987) ("A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference."); *see also Richardson v. Suzuki Motor Co.*, 868 F.2d 1226, 1236 (Fed. Cir. 1989) ("The identical invention must be shown in as complete detail as is contained in the . . . claim."). Independent claim 11 recites:

An apparatus for applying thin sections of a tissue sample to a receiving medium comprising:

a blade assembly for slicing thin sections from a tissue sample;

a plurality of transfer rollers sequentially arranged in tangential proximity to each other, such that a thin section on the surface of one transfer roller will be transferred to the surface of the sequentially successive transfer roller;

wherein a first sequential transfer roller of said plurality of transfer rollers is oriented in proximity to said blade assembly so that said thin section sliced from said tissue sample will contact the surface of said first sequential transfer roller; and



transfer roller ... to the surface of the sequentially successive transfer roller.”  
Therefore, Applicants respectfully request that this rejection be withdrawn.

In addition, McCormick does not disclose its tissue section 26 being transferred from the surface of one of the alleged transfer rollers to the next. Instead, tissue section 26 in McCormick remains on conveyer 24 until it reaches mounting station 60. McCormick, Col. 6, ll. 9-15. Tissue section 26 is never located on a surface of sprocketed wheels 40. In fact, because sprocketed wheels 40 are sprocketed, it is likely that a tissue section would be damaged if it were on the surface of McCormick’s sprocketed wheels.

In order to make this rejection, it appears that the Office Action is reading “surface of said ... sequential transfer roller” in an unreasonably broad manner. For example, the Office Action states that McCormick’s tissue section 26 is on the surface of sprocketed wheel 40 because it “contacts belt 24 which contacts roller 40a, therefore 26 contacts the surface of 40a.” Office Action, Page 6. Contrary to the Office Action’s statement, however, the surface of sprocketed wheels 40a and 40 does not include the intervening conveyer 24. Although conveyer 24 may be in contact with the surface of sprocketed wheels 40a and 40, and tissue section 26 may be on the surface of conveyer 24, this does not mean that tissue section 26 is on the surface of sprocketed wheels 40a and 40. Rather, as admitted by the Office Action, conveyer 24 exists between tissue section 26 and sprocketed wheels 40a and 40, which indicates that tissue sample 26 is not on the surface of sprocketed wheels 40a and 40. Therefore, for at least these reasons, Applicants respectfully request that the rejection of independent 11, and all claims dependent thereon, be withdrawn.

With regard to independent claim 27, the Office Action asserts:



McCormick discloses the same invention including a holding assembly for manipulating a work piece (16), a blade assembly for preparing a thin section from the work piece (18), a transfer roller mechanism (40a, 48, and 40) for transferring the thin section to a receiving medium (62), and a controller (34).

Office Action, Page 7. Applicants respectfully disagree.

Applicants submit that McCormick does not disclose all elements of claim

27. Specifically, claim 27 recites:

An apparatus for automatically producing tissue slides from a tissue sample within a sample block comprising:

a holding assembly for manipulating said sample block;

a blade assembly for preparing a thin section from said sample block;

a transfer roller mechanism for transferring said thin section to a receiving medium; and

a controller.

Appl'n, Claim 27. Referring to Fig. 1 of McCormick, however, the alleged "transfer roller mechanism," which consists of sprocketed wheels 40a and 40 and sprocketed drive wheels 48 do not transfer tissue section 26 to glass slide 62. Instead, McCormick discloses the process as follows:

After undergoing staining, the tissue sections 26 are transported to a mounting station 60 at which the now sterilized and stained tissue sections are transferred from the conveyor 24 to a glass slide 62. To assure adhesion of the tissue sections 26 to the glass slide 62, a methacrylate monomer 64 covers the surface of the glass slide 62. The tissue section 26 is potted in the methacrylate monomer 64 which is then polymerized by exposure to ultraviolet light emitted from an ultraviolet light source 66. This solidifies the methacrylate monomer 64 with the tissue section 26 therein such that the tissue section 26 is affixed to the glass slide 62 for conventional viewing under a microscope 68.

McCormick, Col. 6, ll. 9-21 (emphasis added). Thus, the tissue sample 26 is affixed to glass slide 62 from conveyer 24 via methacrylate monomer 64, and not from any elements of the alleged "transfer roller mechanism." Therefore, Applicants respectfully request that the rejection of independent claim 27, and all claims dependent thereon, be withdrawn.

**E. Claim Rejections under 35 U.S.C. § 103(a)**

**1. Claims 15 and 28**

Claims 15 and 28 stand rejected under 35 U.S.C. § 103(a) as allegedly rendered obvious by McCormick in view of U.S. Patent No. 3,286,575 to Burkhardt. Specifically, with regard to claim 15, the Office Action asserts:

However, McCormick fails to disclose a first blade assembly. Burkhardt teaches a first or preliminary blade assembly (Column 1, lines 33-35). It is also old and well known in the art of manufacturing to cut a work piece down to a specific size so that the work piece fits in the next machine of the manufacturing process. Therefore, it would have been obvious to one of ordinary skill in the art, at the time of the invention, to have provided McCormick, with a first or preliminary blade assembly, as taught by Burkhardt, to cut away unwanted parts of the work piece before the critical cutting takes place.

Office Action, pages 7-8.<sup>2</sup> Applicants respectfully disagree, as the Office Action has failed to establish a prima facie case of obviousness.

In order to establish a prima facie case of obviousness, at least three criteria must be met. First, there must be some motivation or suggestion to make the proposed combination or modification of the references. Notably, "the teaching or suggestion to make the claimed combination must be found in the prior art, and not

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<sup>2</sup> The Office Action presents a similar rejection with regard to claim 28. See Office Action, Page 9.

based on the applicant's disclosure." MPEP 2142, discussing In re Vaeck, 947 F.2d 488 (Fed. Cir. 1991). Second, there must be a reasonable expectation of success. Finally, the combined or modified references must teach or suggest all claim limitations. See MPEP § 2142 *et seq.*

Assuming arguendo that there is motivation to combine McCormick and Burkhardt, the combined references fail to disclose or suggest all claim limitations. Claims 15 and 28 are dependent on independent claims 11 and 27, respectively, and thereby incorporate all limitations of those claims and any intervening claims. 35 U.S.C. § 112, ¶ 4. Contrary to the Office Action's assertions, McCormick does not disclose all elements of independent claims 11 and 27, and Burkhardt does not cure these deficiencies. Therefore, for at least the reasons articulated above with respect to independent claims 11 and 27, Applicants respectfully request that this rejection be withdrawn.

## 2. Claims 16 and 35

Claims 16 and 35 stand rejected under 35 U.S.C. § 103(a) as allegedly rendered obvious by McCormick in view of U.S. Patent No. 6,520,061 to Fukuta et al. ("Fukuta"). Specifically, with regard to these claims, the Office Action asserts:

McCormick discloses the invention but fails to disclose a blade supply canister, a blade take-up canister, and the blade is advanced from the blade supply canister to the blade take-up canister at predetermined intervals. Fukuta et al. teaches that it is old and well known in the art of stationary blade/moving workpiece saw to incorporate a blade supply canister (10-1), a blade take-up canister (10-2), and the blade is capable of being advanced from the blade supply canister to the blade take-up canister at predetermined intervals (column 3 lines 66-67 cont. column 4 lines 1-2). Therefore, it would have been obvious to one of ordinary skill in the art, at the time of the invention, to have provided McCormick, with the slicing means, as taught by Fukuta et al., to provide a longer lasting blade to perform the slicing function.

Office Action, Pages 8. 10. Applicants respectfully disagree, as the Office Action has failed to establish a prima facie case of obviousness.

Applicants submit that Fukuta is not prior art to the present invention. The present application has a priority date of April 9, 1999, the filing date of parent application 09/289,181 (now U.S. Patent No. 6,387,653). Fukuta, on the other hand, has a U.S. filing date of November 3, 1999, after the priority date for the present invention. Therefore, Applicants respectfully request that this rejection be withdrawn.

In any event, the combined references fail to disclose or suggest all claim limitations. Claims 16 and 35 are dependent on independent claims 11 and 27, respectively, and thereby incorporate all limitations of those claims and any intervening claims. 35 U.S.C. § 112, ¶ 4. Contrary to the Office Action's assertions, McCormick does not disclose all elements of independent claims 11 and 27, and Fukuta does not cure these deficiencies. Therefore, for at least the reasons articulated above with respect to independent claims 11 and 27, Applicants respectfully request that this rejection be withdrawn.

### 3. Claim 19

Claim 19 stands rejected under 35 U.S.C. § 103(a) as allegedly rendered obvious by McCormick in view of U.S. Patent No. 6,074,868 to Blumenfeld. Specifically, the Office Action asserts:

McCormick discloses the invention but fails to disclose a display means for displaying operating information. Blumenfeld teaches that it is old and well known in the art of machines adapted to work with slides to incorporate a display means (22b). Therefore, it would have been obvious to one of ordinary skill in the art, at the time of the invention, to have provided McCormick, with a display means, as

taught by Blumenfeld, to allow the productivity of the machine to be watched and corrected if need be.

Office Action, Pages 8-9. Applicants respectfully disagree, as the Office Action has failed to establish a prima facie case of obviousness.

Claim 19 is dependent on independent claim 11, and incorporates all limitations of that claims and any intervening claims. 35 U.S.C. § 112, ¶ 4. Contrary to the Office Action's assertions, McCormick does not disclose all elements of independent claim 11, and Blumenfeld does not cure these deficiencies. Therefore, for at least the reasons articulated above with respect to independent claim 11, Applicants respectfully request that this rejection be withdrawn.

#### 4. Claim 30

Claim 30 stands rejected under 35 U.S.C. § 103(a) as allegedly rendered obvious by McCormick in view of U.S. Patent No. 6,416,959 to Giuliano et al. ("Giuliano").<sup>3</sup> Specifically, the Office Action asserts:

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<sup>3</sup> Applicants submit, however, that Giuliano may not be prior art to the present invention. The present application has a priority date of April 9, 1999, the filing date of parent application 09/289,181 (now U.S. Patent No. 6,387,653). Giuliano, on the other hand, discloses a string of continuation-in-part applications:

Continuation-in-part of application No. 091430,656, filed on Oct. 29, 1999, and a continuation-in-part of application No. 091398,965, filed on Sep. 17, 1999, which is a continuation-in-part of application No. 091352,171, filed on Jul. 12, 1999, which is a continuation-in-part of application No. 091031,271, filed on Feb. 27, 1998, which is a continuation-in-part of application No. 081810,983, filed on Feb. 27, 1997, now Pat. No. 5,989,835.

Giuliano, "Related U.S. Application Data." U.S. Patent No. 5,989,835 does not disclose the "optical imaging system for locating the tissue sample within the

(continued...)

McCormick discloses the invention including the controller determines an orientation of the sample blade with respect to the blade assembly (34). However, McCormick fails to disclose an optical imaging system for locating the tissue sample within the sample block. Giuliano et al. teaches an optical imaging , system for locating the tissue sample within the sample block (21 5 and Column 11 lines 26-40). Therefore, it would have been obvious to one of ordinary skill in the art, at the time of the invention, to have provided McCormick, with an optical imaging system, as taught by Giuliano et al., to allow the user to detect best part of the work piece to slice off and be put onto a slide.

Office Action, Pages 9-10. Applicants respectfully disagree, as the Office Action has failed to establish a prima facie case of obviousness.

Claim 30 is dependent on independent claim 27, and incorporates all limitations of that claims and any intervening claims. 35 U.S.C. § 112, ¶ 4. Contrary to the Office Action's assertions, McCormick does not disclose all elements of independent claim 27, and Giuliano does not cure these deficiencies. Therefore, for at least the reasons articulated above with respect to independent claim 11, Applicants respectfully request that this rejection be withdrawn.

#### **F. Claims 17 and 18**

The Office Action notes that "claims 17 and 18 have not been rejected over prior art. It may or may not be readable over the prior art but cannot be determined at this time in view of the issues under 35 USC § 112." Office Action, Page 10.

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sample block (215 and Column 11 lines 26-40)." Office Action, Page 9. Therefore, this disclosure must have been added subsequent to the filing that resulted in U.S. Patent No. 5,989,835. To the extent that such disclosure was added after April 9, 1999 (e.g., in Application No. 091430,656, filed on Oct. 29, 1999, Application No. 091398,965, filed on Sep. 17, 1999, or Application No. 091352,171, filed on Jul. 12, 1999), Giuliano is not prior art to the present invention.

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Applicants submit that because these claims are dependent on independent claim 11, they are allowable for at least the reasons set forth above.

#### **V. CONCLUSION**

Applicants respectfully submit that the application is in condition for allowance. Applicants believe that no fees are necessary in connection with the filing of this document. In the event any fees are necessary, please charge such fees, including fees for any extensions of time, to the undersigned's Deposit Account No. 50-0206. Should any outstanding issues remain, the Examiner is invited to telephone the undersigned at the number listed below.

Dated: May 10, 2006

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